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No. 03-1237

IN THE
SUPREME COURT OF THE UNITED STATES

MERCK KGaA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. and THE BURNHAM INSTITUTE and TELIOS PHARMACEUTICALS, INC.,

Respondents.

On Petition For a Writ of Certiorari To The United States Court of Appeals For the Federal Circuit

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONER

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Teva v. Pfizer,
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Valley Drug Co. v. Geneva Pharm. Inc.,
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FEDERAL STATUTES

The Drug Price Competition and Patent Term
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Medicare Prescription Drug, Improvement, and
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MISCELLANEOUS

AARP, *Prescription Drug Use Among Persons Age 45+: A Chart Book* (June 2002) *available at*
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AARP et al., *Survey on Prescription Drug Issues and Usage Among Americans Aged 50 and Older* (May 1996) *available at*
http://research.aarp.org/health/find_toc.html 9

Jan Blustein, *Drug Coverage and Drug Purchases By Medicare Beneficiaries with Hypertension*,
19 Health Affairs 219 (2000) 8

Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures, 2002, at*
www.cms.hhs.gov/statistics/nhe/historical/
highlights.asp (last modified Jan. 8, 2004) 7

Centers for Medicare and Medicaid Services,
National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Select Calender Years 1980-2002, at http://www.cms.hhs.gov/
statistics/nhe/historical/t2.asp.
(last modified Jan. 8. 2004) 2

ECU Center on Aging, *ECU Study Reports RX Drugs too Costly for Many Retirees, available at*
http://www.news.ecu.edu/releases/rxcosts.html
(last viewed March 30, 2004) 8

Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* (July 2000) *available at*
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drugod.pdf?docID=726 2

Kaiser Commission on Medicaid and the Uninsured,
Medicaid Outpatient Prescription Drug Benefit: Findings from a National Survey
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Kaiser Family Foundation, *Prescription Drug Trends* (May 2003) *available at* www.kfff.org/rxdrugs/loader.cfm?url+commonspot/getfile.cfm&pageid=14267. 7

Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, NIHCM Issue Brief (Aug. 2000) *available at* http://www.nihcm.org/prescription.pdf. 6

Nicholas Groombridge and Sheryl Calabro, *Integra LifeSciences v. Merck* - Good for Research or Just Good For Research Tool Patent Owners?, 22 Biotechnology L. Rep. 462 (Oct. 2003) 5, 9

Stephen B. Maebius, Richard J. Warbug and Harold C. Wenger, *Preclinical Use of Research Tool in Infringement*, Nat'l L. J, July 7, 2003 5

Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1 (2001) 7

Janice M. Mueller, *Public Access Versus Proprietary Rights in Genomic Information: What is the Proper Role of Intellectual Property Rights?* 6 *J. Health Care L. & Pol'y* 222 (2003) 7

Letter from William D. Novelli, Chief Executive Officer, AARP, to various pharmaceutical company CEOs (Mar. 8, 2004), *available at* http://www.aarp.org/prescriptiondrugs/informed/Articles/a2004-03-08-rxceomembers.html. 3

PhRMA, *Facts About the U.S. Pharmaceutical Industry* (Mar. 2001), *available at* http://www.phrma.org/publications/publications/brochure/leading/lead9.cfm 8

Public Citizen, *New Study Expected to Significantly Overstate Drug Industry R&D Costs* (Nov. 28, 2001) *available at* http://www.publiccitizen.org/pressroom/release.cfm?I=942. 8

Tufts Center for the Study of Drug Development, *Tufts Center for the Study of Drug Development Pegs Cost of New Prescription Medicine at $802 Million* (Nov. 30, 2001) *available* at http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6 8

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICUS CURIAE* OF AARP IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*[1]

AARP is a nonpartisan, nonprofit membership organization of more than 35 million persons, age 50 or older, dedicated to addressing the needs and interests of older Americans. AARP works to foster the health and economic security of individuals as they age, including attempting to ensure access to quality and economical health care.

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[1] No counsel for any party authored any portion of this brief. No persons other than *amicus curiae*, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief. The written consents of the parties have been filed with the Clerk of the Court pursuant to Supreme Court Rule 37.3.

Access to prescription drug treatments is particularly important to the older population which, because of its higher rates of chronic and serious health conditions, has the highest rate of prescription drug use. Persons over 65, although only 13% of the population, account for 34% of all prescriptions dispensed and 42 cents of every dollar expended on prescription drugs.[2]

Spending on prescription drugs has skyrocketed over the last decade. In 1990, national health expenditures on prescription drugs was $40.3 billion, by 2000 it was $121.5 billion. For 2002, it was $162.4 billion.[3] The rising price of prescription drugs has left many older Americans unable to afford necessary medications. Therefore, AARP supports efforts at the state and national levels to increase access to more affordable drugs. To that end, AARP has filed *amicus curiae* briefs in prescription drug litigation such as *Pharm. Research and Mfg. of America v. Walsh*, 538 U.S. 644 (2003)(arguing that extending the Medicaid discount price for pharmaceuticals to all Maine residents did not violate the Medicaid law); *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003) *and Valley Drug Co. v. Geneva Pharm. Inc.*, 344 F.3d 1294 (11th Cir. 2003)(demonstrating how consumers suffer when generic competition is stifled). It also just filed an *amicus* brief in *Teva v. Pfizer*, No. 04-1186 (Fed. Cir. *appeal docketed*, Jan. 23, 2004)(arguing courts should exercise their declaratory judgment authority to decide patent disputes so that non-infringing generic drugs can be sped to market).

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[2] Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010* at 2 (July 2000) *available at* http://www.familiesusa.org/site/DocServer/drugod.pdf?docID=726.

[3] Centers for Medicare and Medicaid Services, *National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Select Calender Years 1980-2002, at* http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp. (last modified Jan. 8. 2004).

AARP strongly supported passage of the newly enacted Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) which created a Medicare prescription drug benefit, as well as altered the Federal Food Drug and Cosmetic Act and patent laws to facilitate bringing lower cost prescription drugs to market sooner.

AARP recently urged sixteen major pharmaceutical companies to limit their price increases for current drug products to no greater than the level of inflation, to constrain the prices of new drugs, and to use their influence to curtail greater markups through the distribution chain to retail.[4]

In this case, the Federal Circuit has interpreted the patent laws so broadly that it defines as patent infringement the fundamental scientific research done in order to develop new medications. *Merck v. Integra*, 331 F.3d 860 (Fed. Cir. 2003). If this decision stands, the inevitable effect will be that the costs of drug development will be driven up even further and it will serve to delay the development of new medicines. Both of these consequences harm older Americans.

In light of the significance of the issues presented by this case, AARP respectfully submits this brief *amicus curiae* urging the Court to decide a question of nationally important federal law and health policy.

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[4] Letter from William D. Novelli, Chief Executive Officer, AARP, to various pharmaceutical company CEOs (Mar. 8, 2004), *available at* http://www.aarp.org/prescriptiondrugs/informed/Articles/a2004-03-08-rxceomembers.html.

REASONS FOR GRANTING THE WRIT

1. The Federal Circuit Decided an Important Question of Federal Law that Should be Reviewed by This Court. The Federal Circuit's Decision Reading Preclinical Drug Research out of the 35 U.S.C. §271(e)(1) Exemption Distorts the Balance Congress Strove to Achieve Between Encouraging Competition While Also Rewarding Innovation.

The Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Amendments) amended the patent laws to include an exemption for developing information necessary to obtain regulatory approval for drugs. 35 U.S.C. § 271(e)(1) (2004). As this Court has acknowledged, the Act was intended to preserve patent holders' rights compromised by the time it took to secure regulatory approval, and, at the same time, prevent a *de facto* patent extension equal to the time it would take a competitor to prepare to comply with the regulatory requirements required to bring a drug or medical device to market. See, *Eli Lilly v. Medtronic*, 496 U.S. 661, 669 (1990) (noting the Act was "designed to respond to two unintended distortions of the . . . patent term produced by the requirement that certain products must receive premarket regulatory approval.") The decision in *Medtronic* broadly construed 35 U.S.C. §271(e)(1), applying it both to medical device manufacturers as well as drug manufacturers, to allow "competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Medtronic*, 496 U.S. at 671.

The Federal Circuit's definition of what is "necessary to obtain regulatory approval" is inconsistent with Congressional intent that competitors be able to prepare to compete without risking patent liabilities. The Federal Circuit's decision constricts the §271(e)(1) exemption too far by finding that the exemption does not apply to preclinical drug research. The aim of the research in this case was to develop the information which is a prerequisite for obtaining drug

approval. That is, identifying a product which could be a useful drug which then could be submitted to the FDA for approval. Without doing the research to identify a candidate for clinical testing required by the FDCA, no entity would be able to submit an application for approval. However, the Federal Circuit finds that this predicate research was not using the "patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." §271(e)(1). This reads the words "reasonably related to the development" of drugs out of the statute. It protects the patented products conceivably useful for further drug development so far that it runs counter to Congressional intent to encourage competitors to prepare to compete thereby providing greater access to new pharmaceuticals more quickly.

In contrast to the *Integra* decision, most other courts believed Congress meant to create a broad experimental use exception and "adopted a broad interpretation of the safe harbor provision by concentrating on the 'reasonably related' language." Nicholas Groombridge and Sheryl Calabro, *Integra LifeSciences v. Merck – Good for Research or Just Good For Research Tool Patent Owners?*, 22 Biotechnology L. Rep. 462, 465-66 (Oct. 2003)(concluding that the decision will serve as a "disincentive to further progress in the treatment and prevention of disease.") *See also*, Stephen B. Maebius, Richard J. Warbug and Harold C. Wenger, *Preclinical Use of Research Tool in Infringement*, Nat'l L. J., July 7, 2003, at 14 (confirming judicial trend had been to expansively interpret the exemption, but that *Integra* drastically reined in the safe harbor holding that "development of generic drugs is within the exemption, anything beyond that will be suspect and is probably an infringing activity.")[5] Because the Federal Circuit is the exclusive venue for intermediate appeal of patent disputes, there can be no conflict between the Circuits. However, the difference between the Federal Circuit's narrow reading of the exemption and most other courts' broad

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[5] Many other countries such as the United Kingdom, Germany, Japan and Korea expressly provide broad experimental use exemptions to patent protections. *Id.*

construction provides a reason that this Court should grant review.

2. The Decision Below Causes the Cost of Drug Development to Rise Resulting in Decreased Access to Pharmaceuticals.

The practical effect of the Hatch Waxman Amendments, as well as other laws, has been to greatly extend intellectual property protection afforded to prescription drugs.

> Over the past two decades, Congress has enacted a series of laws that have greatly increased the "effective patent life" enjoyed by brand name prescription drugs . . . . Considered individually, each of these laws offers a reasonable approach to stimulate pharmaceutical innovation and ensure broad access to new medications. Viewed collectively, the laws have conferred multiple and additive protection on prescription drugs.

Michie I. Hunt, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, NIHCM Issue Brief at 1 (Aug. 2000) *available at* http://www.nihcm.org/prescription.pdf. The "average effective patent life of many new drugs has increased by at least 50 percent between the early 1980s and today." *Id.* The Federal Circuit's decision below serves yet again to increase the protection afforded to biomedical patents and correspondingly decreases the exchange of scientific discovery and discourages competition in the pharmaceutical industry.

Concomitant with the increase in patent protection offered is the rising tide of prescription drug prices, threatening health care advances for persons over 50. Although prescription drug spending constitutes 11% of the total health care spending, it is one of the fastest growing components,

increasing at double digit rates each of the last 7 years.[6] Spending for prescription drugs decelerated only slightly, from 15.9 percent in 2001 to 15.3 percent in 2002, but still outpaced growth in all other health services.[7] Retail prescription prices have increased an average of 7.3% per year from 1992-2002, almost triple the average rate of inflation at 2.5%.[8]

The Federal Circuit's finding that basic preclinical drug research is not the kind of activity Congress intended to exempt from patent protection under 35 U.S.C. § 271(e)(1) will increase the cost of drug development and make it even more difficult for consumers to afford the prescriptions they need. This is because researchers testing a patented product in order to develop information necessary to apply for FDA approval for a different drug will have to pay licensing fees to the patent holder if they want to use the product in their experiments. One professor has suggested that requiring licensing for patented research tools such as receptors used in developing new drug products could pose prohibitive costs "so severe as to impede, postpone, or stop the development of important new products."[9] Whatever the cost of the licensing fees, even if it does not stop development, it will certainly add to the $500 million which the pharmaceutical industry claims is the

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[6] Kaiser Family Foundation, *Prescription Drug Trends* at 1 (May 2003), *available at* www.kfff.org/rxdrugs/loader.cfm?url+commonspot/getfile.cfm&pageid=14267.

[7] Centers for Medicare & Medicaid Services, *Highlights – National Health Expenditures, 2002, at* www.cms.hhs.gov/statistics/nhe/historical/highlights.asp (last modified Jan. 8, 2004).

[8] *Id.*

[9] Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 *Wash. L. Rev.* 1, 7 (2001). *See also*, Janice M. Mueller, *Public Access Versus Proprietary Rights in Genomic Information: What is the Proper Role of Intellectual Property Rights?* 6 *J. Health Care L. & Pol'y* 222, 231 (2003) (noting the costs of obtaining a patent could negatively affect the number of products developed).

average cost of developing a new drug.[10] We can be assured that these costs will ultimately be borne by the consumer who either suffers because drug development is delayed or suffers because as the price of prescriptions rise, fewer people can afford the treatments.

Research has shown that uninsured, older and chronically ill people do without drugs when costs become too great a factor. One study analyzed the relationship between cost and purchases from a national sample of people 65 and older who purchased medication. "A one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year." Jan Blustein, *Drug Coverage and Drug Purchases By Medicare Beneficiaries with Hypertension*, 19 Health Affairs 219, 228 (2000). There is "specific, empirical evidence that financial barriers compel older Americans to forgo needed drug treatment."*Id.*[11]

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[10] PhRMA, *Facts About the U.S. Pharmaceutical Industry* (March 2001), *available at* http://www.phrma.org/publications/publications/brochure/leading/lead9.cfm. What it costs to develop a new drug is the subject of intense debate. A 2001 Tufts Center Study claims it costs $802 million, while Public Citizen argues that the true figure is likely to be at least 75% lower. *Compare* Tufts Center for the Study of Drug Development, *Tufts Center for the Study of Drug Development Pegs Cost of New Prescription Medicine at $802 Million* (Nov. 30, 2001) *available* at http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=6 *with* Public Citizen, *New Study Expected to Significantly Overstate Drug Industry R&D Costs* (Nov. 28, 2001) *available at* http://www.publiccitizen.org/pressroom/release.cfm?ID=942.

[11] In 1997, Sociologist Jim Mitchell and anthropologist Holly Mathews collected information from over 600 persons aged 66 and older. Mitchell and Mathews found that over 30 percent of the people that take prescription drugs had difficulty paying for them, while 15 percent took less medicine than prescribed or went without their medications altogether because they could not afford the drugs. *See* ECU Center on Aging, *ECU Study Reports RX Drugs too Costly for Many Retirees, available at* http://www.news.ecu/edu/releases/rxcosts.html (last viewed March 30, 2004).

A study conducted in 1995 by AARP, the National Pharmaceutical Council and the Pharmaceutical Executive magazine found that for Americans age 50 and older with incomes under $10,000 a year, 37% had to cut back on necessary items such as food or heating fuel to pay for a prescription. AARP et al., *Survey on Prescription Drug Issues and Usage Among Americans Aged 50 and Older* (May 1996) *available at* http://research.aarp.org/health/find_toc.html.

[12] Groombridge, *supra* at 5.

In a March 2002 national survey of Americans aged 45 or older, more than one in five (22%) reported they did not fill at least one prescription prescribed by their doctor during the last two years. AARP, *Prescription Drug Use Among Persons Age 45+: A Chart Book* (June 2002) *available at* http://research.aarp.org/il/rx_charts.pdf. The cost of the drug was the main reason people cited for not getting their prescription filled. *Id.* at 25. Of particular concern is that the proportion of people who say cost was a main reason for not getting a prescription is rising, up from 13% in 1986 to 32% in 2002. *Id.* at 72.

High drug costs are stressing publicly funded drug insurance programs as well as individuals. According to the Kaiser Commission on Medicaid and the Uninsured,"every state has implemented or is planning Medicaid pharmaceutical cost containment activities in FY 2004." Kaiser Commission on Medicaid and the Uninsured, *Medicaid Outpatient Prescription Drug Benefit: Findings from a National Survey* at i (Dec. 2003).

The question of the cost of drug development has a direct impact on access to life saving and health preserving medications. This Court should take this case in order to interpret the breadth of the §271(e)(1), "an issue of huge importance to the biotechnology industry"[12] and perhaps even more importance to the people who need the medicines.

CONCLUSION

For the above reasons, AARP urges the Court to grant the petition for a writ of certiorari.

April 2, 2004

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